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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,337	07/03/2003	Jacob Lavee	25550	3787

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EXAMINER

KRAMER, NICOLE R

ART UNIT PAPER NUMBER

3762

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,337

Applicant(s)

LAVEE ET AL.

Examiner

Nicole R. Kramer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/03/03; 11/24/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claims 14-16, and 28 are objected to because of the following informalities:
"wherein the used" in claim 14 should be --wherein the system is used--, "wherein the where" in claims 15 and 16 should be --wherein--, and "over the limb" in claim 28(b) should be --over the organ--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-5, 7-12, 15-18, 23, and 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,602,182 ("Milbocker"). Milbocker discloses a hydraulic system for supporting a body organ comprising a closed loop liquid-tight tubing (col. 24, line 1) fitted with a pressure generator (energy converter 3) for propelling a liquid through the system, an organ engaging member (pumping unit 1) connected to a pressure chamber (hydraulic reservoir 4) via a discharge valve (outlet valve 9) for controlled discharge of liquid into the organ inflatable pressure member; said organ engaging member comprising an inflatable pressure member suited for receiving the

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organ (cuff having inflatable elements as shown in Figure 16); at least one control valve (inlet valve 10) for selectively controlling liquid flow through the system; and a controller (controller 6) for selectively controlling the discharge valve and the at least one control valve.

With respect to claim 2, Milbocker discloses the organ engaging member comprising a rigid housing (non-distensible sheath) accommodating the inflatable pressure member (inflatable tube elements shown in Fig. 16) (see Abstract).

With respect to claim 3, the organ engaging member is annular (Fig. 16).

With respect to claim 4, the hydraulic liquid flowing through the system is necessarily a physiological acceptable solution since the system disclosed in Milbocker is implantable.

With respect to claim 5, the pressure chamber (hydraulic reservoir 4) is a pressure accumulator (col. 23, lines 62-65).

With respect to claim 7, the pressure discharge valve (outlet valve 9) and the control valve (inlet valve 10) are one-way valves.

With respect to claim 8, the controller (6) is programmable (see claim 15).

With respect to claim 9, the controller (6) generate a control signal responsive to signals corresponding with physiologically-related parameters obtained from the body (col. 24, lines 17-20).

With respect to claims 10-11, the system disclosed in Milbocker is a cardiac assist device where the organ engaging member is fitted around the heart (Fig. 16), and

the controller (6) generates control signals responsive to heart condition signals received from an associated ECG device (col. 24, lines 17-20).

With respect to claim 12, the discharge valve (outlet valve 9) is activated to exercise the organ engaging member at a rate corresponding with the self systolic pace of the heart (col. 23, lines 36-38, col. 25, lines 18-30; col. 26, line 66-col. 27, line 5).

With respect to claims 15-17, the pressure generator (3) may consist of a hydraulic pump (col. 24, lines 13-15). The pump continuously operates (col. 24, lines 15-17).

With respect to claims 28-31, Milbocker discloses a method for stimulating motion to a body organ comprising the steps of obtaining body-organ hydraulic assist system as described, fitting the inflatable pressure member over the organ, activating the pressure generator and the controller, obtaining condition signals indicative to a heart condition from an associated ECG device (col. 26, line 66-col. 27, line 5), and generating a control signal to the valves of the system responsive to said condition signals (col. 24, lines 1-26). The control signals are in cadence with the normal functioning of the heart (col. 23, lines 36-35). The pressure chamber is charged with liquid during the diastolic heart period, and released into the inflatable member during systole (col. 25, lines 18-30).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6, 20-22, 25-27, and 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,602,182 ("Milbocker") in view of U.S. Patent No. 6,770,024 ("Rastegar"). Milbocker discloses applicant's basic inventive concept, a hydraulic system for supporting a body organ as described above. Milbocker accomplishes flow control via a hydraulic pump for continuously pumping fluid between two reservoirs, and utilizes a controller to maintain the reservoirs at their respective pressurized states. Col. 5, lines 48-65. Milbocker fails to disclose a multiple valve hydraulic system including a first one-way valve between the pressure generator and the pressure chamber, a second one-way valve fitted between the organ engaging member and the pressure generator, and a circulation valve mounted in parallel relation to the pressure generator on a tube segment extending between the pressure generator and the first one-way valve that are selectively controlled to accomplish flow control.

Rastegar teaches such a hydraulic system. Rastegar teaches a closed hydraulic system including a first one-way valve (60) between the pressure generator (pump B) and the pressure chamber (expandable reservoir 12), a second one-way valve (56) fitted between an inflatable chamber (35) and the pressure generator, and a circulation valve (52) mounted in parallel relation to the pressure generator on a tube segment extending between the pressure generator and the first one-way valve. The multiple valves of the hydraulic system are selectively controlled via controller (10) to accomplish

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the desired flow control (Figs. 2 and 3). The cardiac assist device as taught in Rastegar operates in a counterpulsation mode, meaning that fluid flow is directed to the inflatable chamber (35) during diastole and away from the inflatable chamber during systole (Abstract).

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the cardiac assistance system of Milbocker to include the multiple valve hydraulic system as taught by Rastegar in order to accomplish flow control of the hydraulic system. As discussed above, Milbocker accomplishes flow control via multiple fluid reservoirs. However, the multi-valve system as taught by Rastegar could also be utilized to accomplish the desired flow control. The valves as taught by Rastegar would be caused to operate in the manner required for operation of the cardiac assistance system disclosed in Milbocker – that is, the controller would cause charging of the reservoir during diastole and releasing the fluid to the inflatable member during systole.

6. Claims 13, 14, 19, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,602,182 ("Milbocker").

As to claims 13 and 14, Milbocker fails to specifically disclose that the hydraulic assist device may be used to as a peristaltic assist device or to stimulate blood flow in a limb. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of

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performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The device in Milbocker is capable of being used to as a peristaltic assist device or to stimulate blood flow in a limb. As to claim 24, Milbocker fails to specifically disclose a system comprising two or more organ engaging members controlled in a peristaltic manner. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to include two of more organ engaging members, since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Co. v. Bemis Co.*, 193 U.S.P.Q. 8.

As to claim 19, Milbocker fails to specifically disclose that the closed loop liquid-tight tubing comprises non-elastic components. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to construct the conduits disclosed in Milbocker of non-elastic components, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 U.S.P.Q. 416.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent Nos. 5,800,334; 5,269,811 and U.S. Patent Application Publication 2004/0225177 A1.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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